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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,037	02/18/2000	SYLVAIN ORENGA	105454	7665

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EXAMINER

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ART UNIT PAPER NUMBER

1645

DATE MAILED: 07/01/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,037

Applicant(s)

Orenga

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 23, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-12, and 19-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-28 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-12, 19, and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicant's amendment filed April 23, 2003 (Paper Number 16) has been received and entered. Claims 3 and 13-18 have been canceled, and new claims 29-31 have been added.

Consequently, claims 1-2, 4-12 and 19-31 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 2-3 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of the term optionally is withdrawn in view of Applicants amendment.
2. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of a "derivative" is withdrawn in view of the cancellation of said claim.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. The rejection of claims 1-4 and 6-8 under 35 U.S.C. 102(b) as being anticipated by Kaneko et al is maintained.

Applicants are asserting that claim 1 has been amended to recite that the compound that selectively inhibits the hexosaminidase activity of *C. tropicalis* is "not formamide." Applicants assert that Kaneko does not disclose such a medium.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants have amended claim 1 to recite that the compound that selectively inhibits the hexosaminidase activity of *C. tropicalis* is "not formamide." However, this limitation is still not sufficient to overcome the disclosure of Kaneko et al. As set forth in the office action mailed October 23, 2002 Kaneko disclose of a composition comprising 5-bromo-4-chloro-3-indolyl- β -D-glucuronic acid and dimethyl formamide. Those of ordinary skill in the art would readily appreciate that dimethyl formamide has a distinct structure from that of formamide

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Consequently, the amendment to recite “not formamide” does not exclude the compound “dimethyl formamide.”

The claims are drawn to culture medium for the specific identification and/or differentiation of *Candida albicans* and *Candida tropicalis* yeast, comprising a chromogenic or fluorogenic substrate, which can be hydrolyzed by an enzyme of the hexosaminidase family, wherein the medium also comprises at least one compound that selectively inhibits the hexosaminidase activity of *C. tropicalis*, wherein said compound is not formamide.

Kaneko et al (U.S. Patent Number 5,272,072) disclose of a composition comprising 5-bromo-4-chloro-3-indolyl- β -D-glucuronic acid and dimethyl formamide. (See column 9).

In view that 5-bromo-4-chloro-3-indolyl- β -D-glucuronic is a chromogenic substrate that can be hydrolyzed by an enzyme of the hexosaminidase family and that dimethyl formamide selectively inhibits the hexosaminidase activity of *C. tropicalis*, the disclosure of Kaneko et al is deemed to anticipate the claimed invention.

It is noted that Kaneko et al do not disclose culturing *Candida* with the composition, however culturing *Candida* with the composition is merely an intended use of the composition and

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5. The rejection of claims 19 under 35 U.S.C. 102(e) as being anticipated by Wong-Madden et al is maintained.

Applicants are asserting that Wong-Madden do not teach a microbiological analysis process for selectively identifying and/or differentiating the *C. albican* and/or *C. tropicalis* yeasts, characterized in that the sample to be analyzed is placed directly in contact with the medium of claim 1.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants attention is directed to claim 19, which recites “microbiological analysis process for selectively identifying the *C. albicans* and/or *C. tropicalis* yeast and/or for differentiating *C. albicans* and *C. tropicalis* yeasts, characterized in that the sample to be analyzed is placed directly in contact with at least one identification medium according to claim 1.”

Applicants have not traversed that Wong-Madden teach the composition of claim 1. Applicants have only asserted that Wong-Madden do not teach the microbiological analysis part. However, Wong-Madden et al have taught the identical composition as claimed in claim 1, and further inoculated a sample into the medium. Consequently, each and every limitation has been addressed by Wong-Madden et al. The claim does not require a step of identifying a certain species of *Candida*, allowing colors to appear in the medium, or anything else to differentiate from what Wong-Madden et al already preformed. “Generally, the preamble does not limit the claims...

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body to define the subject matter of the claimed invention.” Allen Eng’g Corp. v. Bartell Indus., v. Darragh Co., 63 USPQ2d 1769, 1774 (Fed. Cir. 2002). “A statement of intended use or purpose usually will not limit the scope of the claim since such statements merely define the context in which the invention operates. However, preamble language may limit the claim if it recites not merely a context in which the invention may be used, but give meaning to the limitations recited in the body of the claim.” DeGeorge v. Bernier, 226 USPQ 758, 761 n.3 (Fed. Cir. 1985).

In view that the body of the claim merely recites placing a sample in the culture medium of claim 1, and that Wong-Madden et al placed a sample in a medium identical to the medium recited in claim 1, the disclosure of Wong-Madden et al is deemed to anticipate the claimed invention.

The claims are drawn to microbiological analysis process for selectively identifying the *C. albicans* and/or *C. tropicalis* yeast and/or for differentiating *C. albicans* and *C. tropicalis* yeasts, characterized in that the sample to be analyzed is placed directly in contact with at least one identification medium according to claim 1.

Wong-Madden (U.S. Publication 2002/0137176) disclose of multiple chromogenically labeled substrates in a composition. (See pages 6-9).

In view that Wong-Madden disclose of multiple chromogenically labeled substrates that can be hydrolyzed by an enzyme from the hexosaminidase family, and chromogenically labeled

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substrates that can be hydrolyzed by an enzyme from the glucosidase family, and further placing a sample in the medium, the disclosure of Wong-Madden et al is deemed to anticipate the claimed invention.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 112

6. Claims 1-2, 4-12, 19 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to newly recite that the at least one compound that selectively inhibits the hexosaminidase activity of *C. tropicalis*, “wherein said compound is not formamide.” However, Applicants have not pointed to support for claiming an entire genus of compounds that inhibit hexosaminidase while excluding formamide from this list. Furthermore, Applicants claimed composition clearly encompasses formamide. (See claims 9 and 31). Consequently, the newly cited limitation of excluding formamide from the compounds which inhibit the hexosaminidase activity of *C. tropicalis* must have clear support within the originally filed specification. Applicant

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is required to demonstrate this support (page and line number) or cancel the newly added material.

Claims 20-28 are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner